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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,616	04/13/2006	Enea Menegatti	2503-1211	1346

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

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03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,616	MENEGATTI ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 Jan 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 12 Jan 2009, in which claims 1 and 14 are amended to change the scope and breadth of the claim, claim 2 is canceled, and new claim16 is added.

This application is the national stage entry of PCT/EP04/11236, filed 08 Oct 2004; and claims benefit of foreign priority document ITALY MI2003A002019, filed 17 Oct 2003. An English language translation of this foreign priority document has not been made of record.

Claims 1, 3-6 and 8-16 are pending in the current application.

Rejections Withdrawn

Applicant's Amendment, filed 12 Jan 2009, with respect to claims 1-4, 8-9 and 11-13 and new claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) in view of Riley, Jr. (US Patent 5,055,303, issued 08 Oct 1991, of record) has been fully considered and is persuasive, as claim 1 is amended to recite limitations on the concentration of the aqueous phase.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 12 Jan 2009, with respect to claims 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) in view of Riley, Jr. (US Patent 5,055,303, issued 08 Oct 1991, of record) and in view of Smolinske (Handbook of Food, Drug, and Cosmetic Excipients, 1992, p 251, of record) has been fully considered and is persuasive, as claim 1 is amended to recite limitations on the concentration of the aqueous phase.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 12 Jan 2009, with respect to claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) in view of Riley, Jr. (US Patent 5,055,303, issued 08 Oct 1991, of record) and in view of Bonda (US Patent 6,551,605, issued 22

Apr 2003, of record) has been fully considered and is persuasive, as claim 1 is amended to recite limitations on the concentration of the aqueous phase.

This rejection has been **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "active ingredient is from 0.01% to 0.5% in weight" at lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends from claim 1, which recites "comprising a retinoid and a phospholipid emulsifier as active ingredient" (emphasis added) at lines 2-3 and requires said phospholipid emulsifier present in an amount ranging from 10 to 15% by weight. As claim 1 recites both retinoid and a phospholipid emulsifier as active ingredient and requires 10 to 15% by weight of said phospholipid emulsifier, it is unclear how the active ingredient of retinoid and a phospholipid emulsifier can be present in 0.01% to 0.5% in weight required by claim 14. For the purpose of facilitating prosecution, claim 14 has been interpreted as drawn to the concentration of said retinoid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US Patent Application Publication 2005/0031547, filed 28 Apr 2008, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record).

Tamarkin et al., a reference under 35 U.S.C. 102(e), was filed prior to PCT/EP04/11236, filed 08 Oct 2004; but after foreign priority document ITALY MI2003A002019, filed 17 Oct 2003. However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Tamarkin et al. teaches oleaginous emulsions comprising a hydrophobic solvent, surface active agents at a concentration of less than about 10% by weight, and an active agent present at effective concentrations (page 1, paragraphs 13-17). Tamarkin et al. teaches said oleaginous emulsions having less than about 10% by weight water (page 1, paragraph 20). Tamarkin et al. teaches said surface active agents produce oil-in-water microemulsions (page 6, paragraph 118) and said surface active agents consist of the phospholipid phosphatidylcholine (page 7, paragraph 127). Tamarkin et al. teaches the solvent includes the alkyl ester fatty acid isopropyl palmitate (page 5, paragraph 92). Tamarkin et al. teaches said active agent includes the class of retinoids for example isotretinoin (page 12, paragraph 211). Tamarkin et al. teaches the microemulsion includes the antioxidant alpha-tocopherol (page 14, paragraph 238) and embodiments comprising the preservative parabens (page 18, paragraph 331 and paragraph 347 spanning pages 19-20). Tamarkin et al. teaches embodiments of the microemulsion wherein the active agent is present in a concentration of 0.1%, 0.5, 1.0 and 5 (page 18, paragraph 331). Tamarkin et al. teaches teaches the emulsions are applied to the skin and mucosal surfaces (page 18, paragraph 318) which are cutaneous surfaces of a mammal and therefore describe percutaneous absorption, which is absorption through unbroken skin, and are therefore capable of performing the intended recited in instant claim 15.

Tamarkin et al. does not specifically teach the composition wherein the aqueous phase is 0.5 to 2% by weight or comprising sodium hyaluronate having a molecular weight ranging from 50 to 200 kDa present in an amount ranging from 0.001 to 0.1 by

weight (instant claim 1). Tamarkin et al. does not specifically teach the composition further comprising hyaluronic acid (instant claim 8). Tamarkin et al. does not specifically teach the composition comprising sodium hyaluronate as hyalastine (instant claim 16).

Friedman et al. discloses an oil-in-water emulsions wherein the emulsion further comprises a mucoadhesive polymer hyaluronic acid (abstract). Friedman et al. discloses the polymer hyaluronic acid may be present as free acids or salts (column 7, lines 16-17) with a preferred molecular weight of at least 50, 300, or 1,000 kDa (column 7, lines 54-56), and envisions mucoadhesive polymer treated with NaOH to give the sodium salt (column 10, lines 59-60). Friedman et al. teaches the preparation of the emulsion followed by addition of an aqueous solution, or acceptable carrier, containing the hyaluronic acid and excipients such as EDTA, preservatives, and antioxidants is within the level of ordinary skill in the art. Friedman et al. citing Riley Jr., US Patent 5,055,303, as prior art disclosing bioadherent emulsions of the water-in-oil type (column 2, lines 35-40) teaches it is within the level of ordinary skill in the art to apply the teaching of Friedman et al. to water-in-oil emulsions. Friedman teaches the bioadhesive polymer is present in the microparticle usually in a final concentration of 0.01% wt/vol. (column 7, lines 15-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Tamarkin et al. in view of Friedman et al. One of ordinary skill in the art would be motivated to combine Tamarkin et al. in view of Friedman et al. because Friedman et al. teaches bioadhesion is advantageous for drug delivery (Friedman et al. column 1, lines 15-65). One of ordinary skill in the art would have a

reasonable expectation of success in combining Tamarkin et al. in view of Friedman et al. because Tamarkin et al. teaches said composition is compatible with hyaluronic acid (page 14, paragraph 235) and Friedman et al. teaches said bioadhesive polymer is found in the interface between the water and oil (figure 1D in drawing sheet 2) and that it is within the level of ordinary skill in the art to apply the teaching of Friedman et al. to water-in-oil emulsions. Regarding the concentration of the aqueous phase, the range 0.5% to 2% is encompassed by the range "less than about 10% by weight water" taught by Tamarkin et al., and generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, see MPEP 2144.05 IIA. Based on evidence provided by della Valle (US Patent 5,925,626, cited in PTO-892), hyalastine appears to refer to any hyaluronic acid having a molecular weight from about 50,000 to about 100,000 (della Valle column 2, lines 45-60). Therefore, hyaluronic acid having a molecular weight of 50 kDa taught by Friedman et al. is deemed to be hyalastine.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US Patent Application Publication 2005/0031547, filed 28 Apr 2008, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) as applied to claims 1, 3-5 and 8-16 above, and further in view of Bonda (US Patent 6,551,605, issued 22 Apr 2003, of record).

Tamarkin et al., a reference under 35 U.S.C. 102(e), was filed prior to PCT/EP04/11236, filed 08 Oct 2004; but after foreign priority document ITALY MI2003A002019, filed 17 Oct 2003. However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Tamarkin et al. in view of Friedman et al. teaches as above.

Tamarkin et al. in view of Friedman et al. does not specifically teach the retinoid fenretinide (instant claim 6).

Bonda teaches retinoids incorporated into an emulsion known in the prior art as equivalents for the same purpose, specifically isoretinoin, tazarotene, and fenretinide. See Bonda, column 6, lines 21-23 and 26, and exemplified in the composition of example 1, columns 5 and 6, lines 39-57.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Tamarkin et al. in view of Friedman et al. and further in view of Bonda. Tamarkin et al. teaches the composition comprising the general class of retinoids, and Bonda teaches isoretinoin, tazarotene and fenretinide are retinoids known in the prior art as equivalents for the same purpose within the class of retinoids. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious, see MPEP 2144.06 II.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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